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10/018,738	04/04/2002	Vivian de Jesus Quesada Muniz	LEXSA.P25	5070

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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/27/2003

[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/018,738	Applicant(s) Muniz et al.
Examiner Vera Afremova	Art Unit 1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 19, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

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DETAILED ACTION

Election/Restriction

Applicants' election without traverse of the Group I invention (claims 1-18), drawn to a composition for detecting and counting Gram-negative microorganisms, in the Paper No. 7 filed 5/19/2003 is acknowledged.

Claims 19 and 20 were canceled by applicants [Paper No. 7 filed 5/19/2003].

Claim Objections

Claims 1-18 are objected to because of the following informalities:

1. First independent claim should start with a phrase, for example: "A composition ..." and depending claims should start as follows, for example: "The composition according to claim ...".
2. The invention is intended for detection of microorganisms rather than "organisms".

Please, use appropriate and consistent terminology in the claims.

3. Claims 2 and 3 appear to contain some typing error in the phrase "papaic".

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 is rendered indefinite by phrase "wherein it contains". It is uncertain as claimed whether "it" refers to a composition or to a microbial biomass. It is suggested to write, for example: "wherein the composition...".

Claim 1 is indefinite because it recites several times the phrase "mixture" without clear antecedent basis for each mixture of components. It is uncertain as claimed how many mixtures (submixtures) are intended to be within the claimed composition which also appears be a mixed composition or a mixture. It is uncertain as claimed what are ingredients within each mixture (submixture). Thus, the number and contents of each mixture, if more than one are intended, are uncertain as claimed. It is also unclear whether the same ingredient could be within two different mixtures for the purpose of establishing ratio of particular components. For example: substances of protein origins are the organic substances and, thus, it is uncertain what components are included in organic/inorganic mixture and what are included in organic protein mixture in order to determine the ratio. It is uncertain to what mixture inhibitor would be assigned. Thus, assignment of components to the mixture and establishing the intended ratio is impaired.

Claim 7 recites the limitation "the growth inhibitory substances". There is insufficient antecedent basis for this limitation in the composition of claim 1 which recites "inhibitors". Please, use consistent terminology to avoid improper antecedent basis.

Claim 7 is rendered indefinite by the phrase "preferably" because it does not point out whether the limitations following the phrase are part of the claimed invention. See MPEP §

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2173.05(d). It is also uncertain whether one or all inhibitor compounds are within the claimed composition.

Claims 8 and 11 are indefinite because it is uncertain what are “organisms to identify” and, thus, it is uncertain what are alcohol, chromogenic compound and enzymes are intended. Are the “organisms” the Gram positive or Gram-negative microorganisms?

Claims 9, 10, 12 and 14-17 are indefinite because it is uncertain whether “total mass of the mixture” is the mass of the whole mixed composition or the mass of the submixture of organic and inorganic substances. Is the claimed composition a dry composition?

Claim 10 is indefinite because it recites limitations which are not part of the composition of claim 4.

Claim 11 is indefinite because it is uncertain as claimed and as disclosed which alcohol is intended. For example: the Registry file of STN contains 92 various compounds with molecular formula C₃ H₈ O₂. Please, provide chemical name. In the instant office action the claimed alcohol is considered to be “1,2-propanediol” as in the composition of US 5,194,374 which is regarded by applicants as the nearest prototype (specification page 3, par. 2). Further, incorporation of alcohol measured in “ml/L” in the mixture which is measured by weight units, adds to the confusion of the issue of separating ingredients between mixtures (submixtures) and to establishing ratio. It is also unclear whether the claimed compositions is dry mixture or liquid composition. It is unclear whether, for example, water is within the intended inorganic substances.

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Claim 12 is rendered indefinite by the phrase “X-gal” because it is uncertain what are “X-gal” compounds in the lack of definitions in the as-filed specification.

Claims 13-17 are rendered indefinite by the phrase “preferably” because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,723,308 [B].

Claims are directed to a composition for detecting and counting Gram-negative microorganisms wherein the composition comprises mixtures of protein substances, Gram-negative microorganism inhibitors and other organic and inorganic substances, wherein protein substances and Gram-positive microorganism inhibitors are present at ratio 2:2 to 24:1 and wherein organic/inorganic substances and protein substances are present at ratio 0.5:1 to 2:1.

Some claims are further drawn to the use of protein substances such as microbial hydrolyzates or hydrolyzates of natural proteins in the composition. Some claims are further drawn to the use of inhibitors such as bile salts in the composition.

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US 5,723,308 discloses a medium composition for detecting or identifying microorganisms belonging to *Enterobacteriaceae* wherein the composition comprises (see col. 2, lines 42-45) protein substances (tryptose and yeast extract, 24 g), inhibitor of Gram-positive microorganisms (bile salts, 1.5 g) and other organic/inorganic substances (lactose, sodium chloride, guar gum and phenol red, 21.25 g). The ratio of components in the composition of the cited patent is within the claimed ranges and, thus, identical to that is claimed, for example: 24:1.5 and 24:21.25. Thus, the cited composition comprises all elements of the claimed composition. Therefore, the cited patent US 5,723,308 [B] anticipates the claimed invention.

Claims 1, 2, 7, 8, 10, 11, 12, 13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,194,374 [A].

Claims are directed to a composition for detecting and counting Gram-negative microorganisms wherein the composition comprises mixtures of protein substances, Gram-negative microorganism inhibitors and other organic and inorganic substances, wherein protein substances and Gram-positive microorganism inhibitors are present at ratio 2:2 to 24:1 and wherein organic/inorganic substances and protein substances are present at ratio 0.5:1 to 2:1. Some claims are further drawn to the use of protein substances such as microbial hydrolyzates or hydrolyzates of natural proteins in the composition. Some claims are further drawn to the use of inhibitors such as cholic or deoxycholic acids or bile salts in the composition. Some claims are further drawn to the use of silicates, pH indicators, 1,2-propanediol as alcohol, chromogenic

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substances and growth promoting substances for Gram-negative microorganisms in the composition. Some claims are further drawn to the amounts of components, pH, gelling agents or agar in the composition. Some claims are further drawn to the use of growth promoting substances for Gram-negative microorganisms such as salts of magnesium, sodium carbonate and low molecular weight nitrogen compounds in the composition.

US 5,194,374 discloses a medium composition for detecting or identifying Gram-negative microorganisms such as *Salmonella* wherein the composition comprises (see example 2) protein substances (peptones and yeast extract, 7 g), inhibitor of Gram-positive microorganisms (deoxycholate, 1 g) and inorganic substances (silica, 16 g). The ratio of components in the composition of the cited patent is substantially identical to that claimed, for example: 7:1 and 16:7 , particularly in view that the cited composition is suitable for detection of the same microorganisms as intended for the claimed invention including *Salmonella* and in view that assignment of ingredients to each submixture is uncertain as claimed. The composition of the cited patent also comprises pH indicator such as neutral red (0.03 g for about 50 g of the total dry mixture or 0.06% in total dry mixture), alcohol such as 1,2-propanediol (10 g/L), chromogenic substances including X-gal beta-glucosidase substrate such as bromochloroindoxylgalactoside (0.1 g for about 50 g of the total dry mixture or 0.2% in total dry mixture), growth promoting substances for Gram-negative microorganisms such as water and gelling agent or agar (example 2). With respect to claim 13 it is noted that the cited composition contains at least some amounts of sodium, magnesium and/or nitrogen compounds of low molecular weight are within the yeast

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extract, for example. The cited composition for detecting and culturing *Salmonella* is considered to have a neutral pH and thus, it is within the claimed range 6.8-7.4 particularly in view that the claimed composition is intended for detecting the same microorganisms including *Salmonella* which are cultured at the same pH as the cited composition.

Thus, the cited composition comprises all elements of the claimed composition.

Therefore, the cited patent US 5,194,374 [A] anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,194,374 [A] taken with the references by Atlas [U] and by Davis et al. [V].

Claims are directed to a composition for detecting and counting Gram-negative microorganisms wherein the composition comprises mixtures of protein substances, Gram-negative microorganism inhibitors, organic and inorganic substances, wherein protein substances and Gram-positive microorganism inhibitors are present at ratio 2:2 to 24:1 and wherein organic and inorganic substances and protein substances are present at ratio 0.5:1 to 2:1. Some claims are further drawn to the use of protein substances such as microbial hydrolyzates or hydrolyzates of

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other natural proteins in the composition. Some claims are further drawn to the use of inhibitors such as cholic or deoxycholic acids or bile salts in the composition. Some claims are further drawn to the use of silicates, pH indicators, 1,2-propanediol as alcohol, chromogenic substances and growth promoting substances for Gram-negative microorganisms. Some claims are further drawn to the amounts of components, pH, gelling agents or agar in the composition. Some claims are further drawn to the use of growth promoting substances for Gram-negative microorganisms such as magnesium chloride, sodium carbonate, creatine, cystine and/or cysteine in the composition.

US 5,194,374 [A] is relied upon as explained above for the disclosure of a microbial culture medium composition intended for the same purpose as the claimed invention such as detecting or identifying Gram-negative microorganisms including *Salmonella* wherein the composition comprises protein substances, inhibitor of Gram-positive microorganisms and other organic/inorganic substances with the same ratio of components as required by the claimed invention. The major ingredients of the cited compositions are the same as required by the claimed invention as explained above. The cited patent teaches incorporation of yeast extract and other peptones or hydrolyzates of natural proteins but it is silent with regard to origins of natural proteins. The cited patent is missing disclosure of some other organic/inorganic ingredients commonly used in the media for detecting or identifying Gram-negative microorganisms including *Salmonella* such as magnesium chloride, sodium carbonate, creatine, cystine and/or cysteine.

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The references by Atlas [U] and by Davis et al. [V] are relied upon for the missing disclosure.

For example: the references by Atlas [U] teaches a large variety of microbial media including media for detecting or identifying Gram-negative microorganisms including *Salmonella* wherein the media comprise cystine and/or cysteine, salts of magnesium and sodium, chlorides and carbonates (page 507, page 763, page 799, page 871) as well as natural protein hydrolysates or substances including beef, yeast, milk and egg proteins or hydrolyzates (pages 507, 788, 799, 871 and 872).

The reference Davis et al. [V] teaches the use of creatine in the medium for intended for selective killing of Gram-positive and Gram-negative microorganisms including *Salmonella* (abstract or Fig. 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the medium composition of US 5,194,374 [A] by adding ingredients which are commonly used in the microbial media as taught by Atlas [U] and Davis et al. [V] with a reasonable expectation of success in detecting or identifying Gram-negative microorganisms including *Salmonella* because all claimed medium ingredients have been known and used in the microbiological media for selection and/or enrichment of Gram-negative microorganisms including *Salmonella*. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The

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idea for combining them flows logically from their having been used individually in the prior art.

In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The use of particular amounts or concentration ranges of particular ingredients are considered to be within the purview of one having ordinary skill in the art of microbiological media. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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June 26, 2003

VERA AFREMOVA

PATENT EXAMINER

